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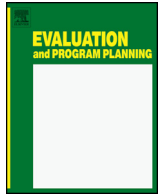
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Design and development of a film-based intervention about teenage men and unintended pregnancy: Applying the Medical Research Council framework in practice



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ABSTRACT

Following the UK Medical Research Council's (MRC) guidelines for the development and evaluation of complex interventions, this study aimed to design, develop and optimise an educational intervention about young men and unintended teenage pregnancy based around an interactive film. The process involved identification of the relevant evidence base, development of a theoretical understanding of the phenomenon of unintended teenage pregnancy in relation to young men, and exploratory mixed methods research. The result was an evidence-based, theory-informed, user-endorsed intervention designed to meet the much neglected pregnancy education needs of teenage men and intended to increase both boys' and girls' intentions to avoid an unplanned pregnancy during adolescence. In prioritising the development phase, this paper addresses a gap in the literature on the processes of research-informed intervention design. It illustrates the application of the MRC guidelines in practice while offering a critique and additional guidance to programme developers on the MRC prescribed processes of developing interventions. Key lessons learned were: (1) know and engage the target population and engage gatekeepers in addressing contextual complexities; (2) know the targeted behaviours and model a process of change; and (3) look beyond development to evaluation and implementation.

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Background

Teenage pregnancy rates in the US and UK remain among the highest in the developed world (Finer and Zolna, 2011) and their reduction is on the international policy agenda (US Department of Health and Human Services, 2010; World Health Organisation, 2013). While the life course for teenage parents is not universally negative (Bonell, 2004), unintended adolescent pregnancy has been associated with poor outcomes for adolescents, their infants and society. Teenage parents are less likely to be in education or employment and more liable to experience social and economic deprivation and poorer physical and psychological outcomes than

their peers (Finer & Zolna, 2011; Harden, Brunton, Fletcher, & Oakley, 2009).

It is recognised that unintended teenage pregnancy results from complex interactions between a broad range of social, cultural, familial and individual level factors (DiCenso, Guyatt, Willan, & Griffith, 2002). Reflecting the complex impacts of these (and the effects of research specific factors such as difficulties with fidelity to implementation protocol), some large-scale behavioural interventions targeting the sexual risk-taking behaviour of young people have only had modest success (DiCenso et al., 2002; Shepherd et al., 2010). It is therefore recognised that school-based Relationship and Sexuality Education (RSE) is but one component in the strategy to reduce teenage pregnancy rates (Elliott, Henderson, Nixon, & Wight, 2013). High quality RSE does, however, contribute to ensuring holistic sexual health by providing adolescents with a solid knowledge base on which to make informed decisions relating to relationships and sexuality (Lindberg & Maddow-Zimet, 2012; Shepherd et al., 2010). Internationally, researchers and policy makers have called for targeted and

Abbreviations: MRC, United Kingdom Medical Research Council; RSE, relationship and sexuality education.

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scientifically evaluated RSE programmes (Downing, Jones, Cook, & Bellis, 2006; Oranganje et al., 2009; Swann, Bowe, McCormick, & Kosmin, 2003). In particular, the need for RSE interventions which meet the sexual health needs of young men has been prioritised (Juszczak & Ammerman, 2011; Saewyc, 2012) and teenage men have been especially neglected in relation to pregnancy related RSE (Alan Guttmacher Institute, 2002; Lindberg & Kost, 2014; Marsiglio, 2006; Saewyc, 2012; Smith, Guthrie, & Oakley, 2005; Swann et al., 2003). When they do receive RSE concerning pregnancy, it is often via programmes and interventions that are directed towards girls and which ignore the fact that males and females are affected differently by gender norms and values relating to pregnancy. Thus, the World Health Organisation has highlighted the urgent need to produce and scientifically evaluate gender-sensitive interventions to address teenage pregnancy (World Health Organisation, 2011).

In providing guidelines for the development and evaluation of complex interventions of this kind, the UK's Medical Research Council, 2008 recommend that high quality evaluation is preceded with a systematic approach to intervention development. The iterative four-phase approach outlined in the MRC framework (Fig. 1) involves developmental work (referred to as 'Phase 1' research) which includes: identification of the evidence base; identification or development of theory relating to the phenomenon of interest; and modelling of processes and outcomes to inform optimisation of the intervention prior to evaluation. However, detailed reports of this developmental process in relation to RSE interventions are scant in the literature [for exceptions see (Carswell, McCarthy, Murray, & Bailey, 2012; Kirby, Coyle, Alton, Roller, & Robin, 2011; McCarthy et al., 2012; Wight & Abraham, 2000)]. The result is a paucity of models which might guide comparable research and the potential for 'reinvention of the wheel' as a result of ineffective process-related knowledge translation and dissemination strategies.

As well as detailing the development and optimisation of an evidence-based, theory-informed intervention which might be applied internationally, in this article our intention is to provide an example of the application of the MRC framework in practice. In applying it in the real world we learned a number of lessons, which both complement and extend beyond the guidance which accompanies the framework. These we offer as core lessons underpinning a model of intervention development to guide the efforts of researchers and practitioners in sex education and, more broadly, researchers engaged in the development and evaluation of complex public health programmes.

Overview of the intervention

Our intervention is entitled *If I Were Jack*. It is based around an interactive video drama (IVD) which presents a hypothetical scenario of a week in the life of Jack, a teenager who has just found out that his girlfriend is pregnant. It is interactive in that the film pauses throughout with questions which invite users to imagine being Jack. On individual computers, they watch Jack as he thinks about what his friends and parents might say, chats to his girlfriend and attends a pregnancy counselling session. The user answers questions about how they would think, feel and react in these situations and ultimately decide upon a pregnancy resolution option. It is intended for use by teenagers aged 14–17 and to be delivered by teachers in classroom settings. Although targeted specifically at young men, it can also be used by young women and in mixed sex classrooms. By asking both girls and boys to empathise with Jack, it is designed to make explicit the gender assumptions around roles and responsibilities for teenage pregnancy while opening them up for reflection and negotiation.

The intervention includes eleven different activities which provide pupils with educational information and opportunities for communication with peers and parents, skills practice, reflection, and anticipatory thinking. A core component is the *If I Were Jack* interactive video drama (IVD) which presents a hypothetical teenage pregnancy scenario from a teenage man's point of view. It invites users to empathise with the main character Jack and ask themselves how they would think and feel if they were in his situation. Additional components which are based around the IVD, including classroom materials, a training session for teachers and an information and discussion session for parents, are detailed in Table 1. Further information about the intervention, including excerpts from the film, is available from the project website <http://www.qub.ac.uk/sites/IfIWereJack>.

The intervention is designed to increase adolescents' intentions to avoid an unintended pregnancy by delaying sexual intercourse or consistently using contraception in sexual relationships. To achieve this impact, it targets six psychosocial mechanisms which theory and research suggest are key to decreasing sexual risk-taking behaviour: knowledge; skills; beliefs about consequences; other socio-cultural influences such as peer norms, gender norms and parental values and beliefs; beliefs about capabilities; and intentions (Ajzen & Madden, 1986; Cane, O'Connor, & Michie, 2012; Michie, Johnston, Abraham, Francis, & Eccles, 2013; Ravis, Sheeran, & Armitage, 2009). It aims to maximise potential impact

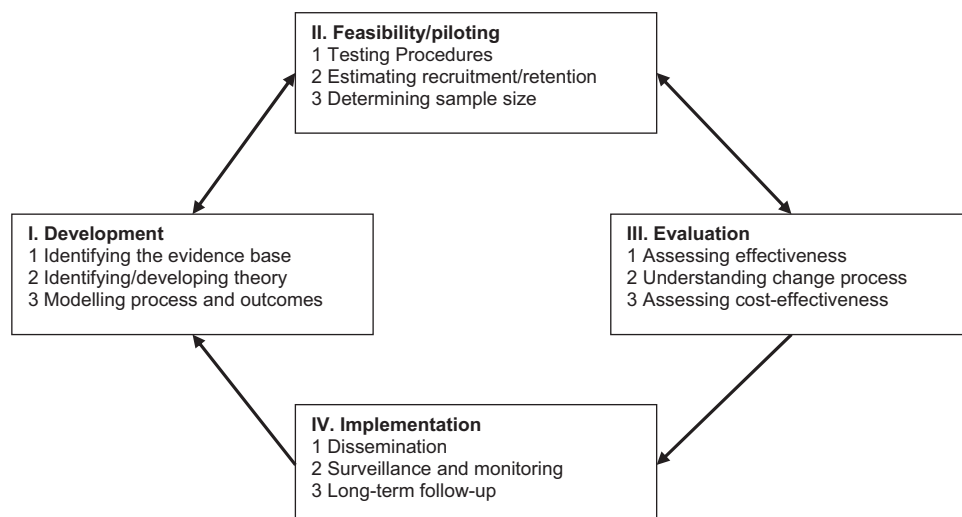


Fig. 1. Key phases in the development and evaluation of complex interventions (: 8).

Table 1

If I Were Jack key components, content and educational objectives.

When	Component	Content	Educational objectives
Pre-intervention	Teacher training session (60 min, online video and discussion forum)	<ul style="list-style-type: none"> • Overview of the resource and its aims and objectives • Demonstration of the IVD • Overview of the classroom materials • Overview of the parent discussion session • Tips on successful delivery • Sources of further information 	<p>By the end of the session teachers should</p> <ul style="list-style-type: none"> • Have a clear understanding of the content and components of the intervention • Understand its key messages and educational objectives • Feel confident in being able to deliver the intervention • Understand the importance of fidelity to implementation protocol • Have had an opportunity to ask questions • Know where to access the resource and sources of further information
Pre-intervention	Parent information and discussion session (60 min, teacher-led)	<ul style="list-style-type: none"> • Overview of the session • Introduction ice-breaker • Overview of the resource and its key messages • Watch the <i>If I Were Jack</i> IVD • Discussion: (a) views on the IVD (b) How would you respond if Jack was your son or Emma your daughter? (c) Do we send different messages to our sons and daughters about pregnancy? (d) What can we do to prevent teenage pregnancy? (e) Talking about relationships and sexuality with our teenagers: challenges and tips • Wrap-up • Parents provided with <i>If I Were Jack</i> parents' factsheet which contains an overview of the resource; facts and myths about teenage pregnancy; tips for speaking to teenagers about relationships and sexuality; and sources of further information 	<p>By the end of the session parents should</p> <ul style="list-style-type: none"> • Have a clear understanding of the content and components of the intervention • Understand its key messages • Feel confident in being able to complete the parent/guardian survey with their teenager • Have had an opportunity to ask questions • Know where to access the resource and sources of further information
Week 1	<p><i>If I Were Jack</i> overview and ground rules</p> <p><i>If I Were Jack</i> interactive video drama (IVD)</p> <p>Homework: 'If I had a baby' activity and 'Jack Factsheet'</p>	<ul style="list-style-type: none"> • Teacher provides overview of the resource and its key messages • Sets ground rules emphasising the need for respect, involvement, confidentiality, and equality • Pupils spend 25 min on individual computers with headphones. Watch film depicting a week in the life of 16-year-old Jack, whom has just found out that his girlfriend is unexpectedly pregnant and respond to on-screen questions when prompted. Questions ask the user to consider what they would do/think/feel if they were Jack • If individual computers not available teacher shows the film on overhead screen and pupils complete paper questionnaires containing questions embedded in the IVD • The 'If I had a baby' activity asks the pupil to complete a worksheet which compares the schedule of a six-month old baby and parent to their own current schedule and to consider the impact that having a baby might have on their current life and future goals • Factsheet contains an overview of the resource; facts and myths about teenage pregnancy; and sources of further information about relationships, sexuality and unintended pregnancy 	<p>By the end of the lesson pupils should be able to</p> <ul style="list-style-type: none"> • Recognise that unintended teenage pregnancy can be a stressful experience and can have some negative consequences • Begin to understand the roles and responsibilities of young men in relation to unintended pregnancy • Recognise the impact that having a baby would have on their daily life
Week 2	<p>Group discussion: If I had a baby activity and Jack Factsheet</p> <p>Group discussion: pause/fast-forward/rewind activity</p> <p>Homework: 'Online scavenger hunt' activity</p>	<ul style="list-style-type: none"> • Group discussion about the homework activities with particular focus on the potentially negative consequences that an unplanned pregnancy might have on their current life and future goals • Pupils think about and discuss Jack and Emma's story and the implications the pregnancy might have for their current situation and future and how they might have avoided an unplanned pregnancy • The 'online scavenger hunt' worksheet contains a list of four websites and four questions. Pupils must access the websites (which relate to sources of information about relationships and sexuality and unintended pregnancy support services) in order to find the answers to the questions • A fifth question requires pupils to find a website with information that might be useful for teenage boys 	<p>By the end of the lesson pupils should be able to</p> <ul style="list-style-type: none"> • Recognise that unintended teenage pregnancy is a stressful experience and can involve some very difficult decisions • Identify potential consequences of unintended teenage pregnancy • Identify the means of preventing unintended pregnancy • Demonstrate their knowledge of local counselling services and sources of online information related to unintended pregnancy and sexual health

Table 1 (Continued)

When	Component	Content	Educational objectives
Week 3	Group discussion: Online scavenger hunt	<ul style="list-style-type: none"> Group discussion based around the answers to the questions in the homework task Discuss whether or not they think there is enough information available for young men 	<p>By the end of the lesson pupils should be able to</p> <ul style="list-style-type: none"> Identify the potential consequences of unintended teenage pregnancy Demonstrate that they could offer advice and accurate information to someone who was experiencing an unintended pregnancy Demonstrate effective communication about unintended pregnancy
	Small group work and discussion: making a difficult decision	<ul style="list-style-type: none"> Brainstorm the consequences of the different pregnancy resolution options referred to in the video and discuss how this would be a difficult decision affected by individual values Work in small groups and use the 'making a difficult decision' worksheet to think about the short- and long-term advantages and disadvantages of each of the options 	
	Small group work and discussion: dilemmas	<ul style="list-style-type: none"> Practice giving advice on 'real-life' dilemmas (four fictional emails) using the knowledge that they have gained about unintended pregnancy 	
	Homework: 'parent/guardian survey'	<ul style="list-style-type: none"> Pupils ask one or both of their parents or guardians (or another trusted adult) to watch If I Were Jack (or read an excerpt of the script) and then ask them the questions on the 'parent/guardian survey' worksheet 	
Week 4	Group discussion: parent/guardian survey	<ul style="list-style-type: none"> Discussion about pupils' experiences of doing the parent/guardian survey 	<p>By the end of the lesson pupils should be able to</p> <ul style="list-style-type: none"> Discuss the roles and responsibilities of young men and young women in relation to unintended pregnancy and how these are affected by gender stereotypes Demonstrate effective communication about unintended pregnancy Recognise the importance of deciding on a plan to ensure that they avoid unintended pregnancy
	Group discussion: 'controversial statements'	<ul style="list-style-type: none"> A discussion activity that encourages pupils to consider stereotypical norms relating to gender and social class and how they relate to sexuality and pregnancy 	
	Role-play activity	<ul style="list-style-type: none"> Work in small groups to write and perform one of four role plays depicting conversations relating to relationships and pregnancy Whole group feedback to performers regarding what they did well and/or could have done better 	
	Wrap-up: complete 'my plan' activity	<ul style="list-style-type: none"> Individual worksheets which encourage pupils to think about how they would feel if they or their partner was pregnant now; the circumstances under which they would like to have a baby in the future e.g. when finished studying, married etc. and to formulate a plan for avoiding an unintended pregnancy 	

by including components, which some studies have indicated are key elements of effective RSE interventions [e.g. interactive media (Bailey et al., 2010; Guse et al., 2012); peer discussion (Oringanje et al., 2009; Wight, Abraham, & Scott, 1998); and parental involvement (Grossman, Frye, Charmaraman, & Erkut, 2013)].

In brief, we hypothesise that by encouraging personal identification with the unintended pregnancy scenario in the IVD we engage pupils in an exercise of the imagination whereby they stop and think about the consequences that an unintended pregnancy might have on their current life and future goals. This identification and reflection process is reinforced by providing knowledge about the risks and consequences of unintended pregnancy and ways to avoid it and offering opportunities to practice communicating about unintended pregnancy with peers and parents (activities which also increase awareness of peer norms and personal and familial values and beliefs about sexual behaviour and unintended pregnancy). We hypothesise that by targeting these psychosocial factors we impact on teenagers' sexual behaviour via pathways through their intention to avoid unintended pregnancy.

Methods

The intervention was developed during two stages. Fig. 2 provides an overview of the tasks involved in the process which, although different in detail, resonate closely with those recommended by the MRC framework—identification of the evidence base; identification of theory relating to the phenomenon of young men and teenage pregnancy; and modelling of processes and outcomes through preliminary research. As outlined in the right hand column of Fig. 2, we began with a systematic review of the literature (Lohan et al., 2010) on adolescent men and unintended

pregnancy. We then developed a version of the IVD as a data collection tool and used this to develop the empirical evidence base on adolescent men's attitudes and decision-making in relation to an unintended pregnancy (Lohan et al., 2011). From the outset we received feedback from pupils, teachers and educational specialists that this version of the IVD had potential to be re-developed as part of an intervention. We then moved to stage 2 and repeated the process specified by the MRC guidelines beginning with a review of the literature on the characteristics of effective RSE. We also re-developed the IVD and filmed a new Northern Irish version (given the contentious cultural differences between Ireland and Northern Ireland) and developed the additional intervention materials which were informed by a theory of change model and our consultations with stakeholders. Below we describe the stages of intervention development and optimisation in detail. Ethical approval for the study was gained (ref: 04.02.02.V2)..

Results

Stage 1: Preliminary research and development of the IVD

Systematic review

The literature on young men's attitudes towards unintended pregnancy and parenthood indicated a number of potential psychosocial influences on young men's attitudes towards adolescent pregnancy and pregnancy outcome decisions (Lohan et al., 2010). These included: social class; religiosity; gender identity; masculinity; the idealisation of pregnancy and parenthood; and attitudes and subjective norms regarding how significant others (such as partners, friends and parents) would expect them to behave

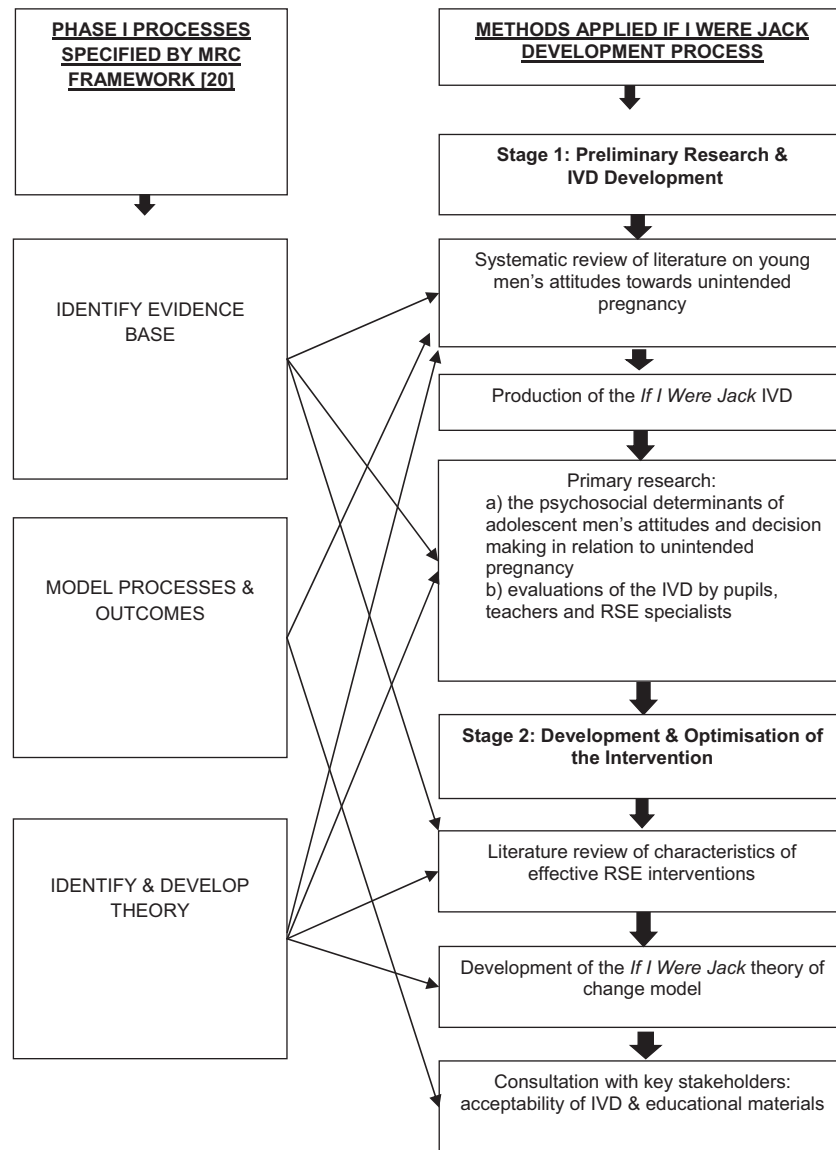


Fig. 2. The *If I Were Jack* development process.

in such a situation. Among these, religiosity and social class emerged as the most important influences on adolescent men's attitudes towards unintended pregnancy and unintended pregnancy outcomes. The review also suggested, however, that factors such as attitudes, subjective norms, and idealisation of pregnancy and parenthood deserve further investigation. These findings informed the development of the data collection tool used during the primary research described below and, later, were included as key mechanisms targeted by the *If I Were Jack* intervention.

Production of the *If I Were Jack* IVD

The *If I Were Jack* IVD was inspired by an Australian version (*If I Were Ben*) which had been used as part of an Australian study of adolescent men and pregnancy (Condon, Corkindale, Russell, & Quinlivan, 2006). The Australian team had developed a film script and interactive questions for *If I Were Ben* by drawing on material from focus group and paired interviews with young people in Australia. With permission, we amended the Australian script and produced and filmed Irish and Northern Irish versions for use as a data collection tool in a study examining influences on young Irish

men's attitudes and decision making in relation to a hypothetical unintended pregnancy (Lohan et al., 2011). Adaptations were based on previous Irish research (e.g. Hyde, Howlett, Brady, & Drennan, 2005) as well as consultation with the study's expert advisory group and script readings with adolescents in three youth drama groups.

The aim of adapting the Australian version of the IVD was to allow the user to have the greatest opportunity to identify with the lead character and his cultural context, especially as legislation and cultural norms on abortion vary considerably between Australia and Ireland (Lohan et al., 2013). Aside from the use of Irish/Northern Irish actors in Irish/Northern Irish contexts, other minor changes were made including vernacular modifications and altered scene-settings such as substituting Irish parks for Australian beaches and riding bikes for driving cars. There were also more substantial changes, such as including a third pregnancy outcome choice ('adoption' in addition to 'keeping the baby' and 'abortion'). This reflects a growing international policy interest in adoption (Resnick, 1992) and, more specific to Ireland, legislation on abortion information requires that the adoption option is discussed and

raised in unintended pregnancy counselling. The film was made interactive by use of Adobe Director software whereby participants' answers to the *If I Were Jack* questions were automatically saved to the computer programme.

Primary research

The Irish version of the *If I Were Jack* IVD was used as a data collection tool in a cross-sectional survey of adolescent men ($N = 360$) aged between 14 and 17 attending schools in Ireland. The study examined their responses to the hypothetical pregnancy scenario depicted in the IVD. This research, which is described elsewhere (Lohan et al., 2011, 2012), emphasised the importance of distal (socio-cultural) variables, notably religiosity, as well as proximal variables, such as the importance of mothers' views and anticipated regret, as determinants of young men's responses to a hypothetical unintended pregnancy. As discussed below, these factors were considered during the development process and, where possible, included as mediating variables to be targeted by the intervention (see Fig. 3).

Evaluations of the *If I Were Jack* IVD with the same research participants supported the notion of developing it as an educational resource and offered suggestions for how it might be optimised for use in the classroom (Lohan et al., 2012). Participants agreed that it was authentic in its representation of a believable unintended teenage pregnancy scenario; engaging to users because of its interactive modality; unique in its representation of the male role in unintended pregnancy and use of high quality drama; easy to use; and held potential for inclusion within the broader RSE curriculum (Lohan et al., 2012). Formative evaluations with the total sample of adolescent males in Ireland ($N = 360$), and a comparable sample in South Australia in relation to the original *If I Were Ben* IVD, also suggested that the IVD had potential for achieving key educational and health promotion outcomes in relation to raising awareness around unintended pregnancy in young men's lives (Lohan et al., 2013) (see Table 2). These results encouraged the research team to move forward with the re-development of the IVD as the cornerstone of a new gender sensitive intervention to explicitly address teenage men's roles in preventing unintended pregnancy.

While the decision to develop and evaluate the existing IVD into an educational intervention was made fairly early in the process, it was based on enthusiastic recommendations by end-users that the existing film would be a valued educational resource for use in the classroom. We were aware that such a decision, made while research examining the determinants of young men's attitudes towards unintended pregnancy was ongoing, had the potential to exclude alternative intervention components and behaviour change theories. We therefore returned, during Stage 2, to develop

the IVD further and to expand the intervention components so that it took into account, as much as possible, the best available evidence regarding the characteristics of effective RSE interventions at that time.

Stage 2: Development and optimisation of the intervention

Stage 2 was explicitly about developing the intervention. It involved re-developing the IVD and designing classroom materials based on evidence regarding the characteristics of effective RSE interventions and theoretical understandings of the determinants of behavioural change.

Also central to stage 2 was collaboration with a multidisciplinary steering group (with health and education experts from statutory departments of health and education in Ireland and Northern Ireland) as well as consultation with end users including teachers, young people and parents and a pre-pilot run in two schools which explored the acceptability and feasibility of the intervention. Stage 2 proceeded as follows.

Consulting on the content

The initial steering group workshop involved discussion of how experts thought the IVD might best be re-developed as an educational resource for inclusion in the RSE curricula across two jurisdictions (Ireland and Northern Ireland) and their views on the content of the classroom materials. They offered advice about where in the curricula the intervention might fit and advised on practical steps to optimise acceptability and feasibility, for example, ensuring that activities could be easily delivered within the constraints of a 35–40 min lesson.

Identifying the evidence and modelling theory

Identifying evidence. A number of systematic reviews have identified the characteristics of RSE interventions which have been effective in changing sexual risk-taking behaviours (Bailey et al., 2010; Guse et al., 2012; Kirby, 2002; Robin et al., 2004; Shepherd et al., 2010). The *If I Were Jack* intervention represents an innovative combination of these different elements. In particular, as recommended by research evidence, it: (1) targets a specific group of individuals (young men) (Marsiglio, 2006; World Health Organisation, 2011); (2) ensures the engagement of pupils by addressing the operation of gender norms, age-appropriateness, and cultural relevance (Shepherd et al., 2010); (3) includes computer-based interactive media (Bailey et al., 2010; Guse et al., 2012); (4) creates opportunities for pro-social communication between and within peer groups (Wight et al., 1998); (5) strengthens the necessary skills which parents and young people need to communicate about pregnancy-related issues (Oringanje et al., 2009; Wight & Fullerton, 2013) and (6) as discussed next, is theory-based (Bailey et al., 2010; Jones, Bates, Downing, Sumnall, & Bellis, 2009).

Modelling theory. Providing a theoretically informed foundation for sexual health education programmes is considered key to effectiveness because it ensures that the most important determinants of young people's sexual behaviour are targeted (Bailey et al., 2010; Downing et al., 2006; Wight et al., 1998). The *If I Were Jack* intervention is broadly based around the Theory of Planned Behaviour (Ajzen & Madden, 1986) but also draws on other psychosocial theories which emerged as important in the research team's systematic review of the literature on adolescent men's attitudes and decision-making in relation to an unintended pregnancy (Lohan et al., 2010). The resulting theoretical framework combines theories of behaviour change (Ajzen & Madden, 1986; Cane et al., 2012; Michie et al., 2013; Ravis et al.,

Table 2
Formative evaluation of the impact of the IVD (Lohan et al., 2013).

Impact on adolescents	Ireland ($N = 360$) strongly agree/agree (%)	Australia ($N = 386$) strongly agree/agree
Got me involved in Jack's/(Ben's) situation	72	60%
Made me think about issues I hadn't thought about before	79	70%
Helped me understand the effect an unplanned pregnancy would have on a guy like me	85	72%
Made me think that I should never get myself in that situation	79	69%
Made me aware that I could talk to a counselling service if I were in Jack's situation	84	n/a

2009) with a sociological understanding of the broader socio-cultural influences and underlying values (especially relating to gender norms, religiosity and social class) and sociological theories such as symbolic interactionism (Gagnon & Simon, 2005) which emphasise the importance of practicing explicit verbal scripts in interpersonal interactions as a means of enhancing communication skills and feelings of self-efficacy in relation to behaviour change.

As illustrated in the *If I Were Jack* theory of change model (Fig. 3), the intervention is hypothesised to impact on young people's sexual behaviours via its influence on the strength of their intentions to avoid unplanned teenage pregnancy. Intention is, in turn, hypothesised to be influenced both directly and indirectly by a range of psychosocial mechanisms which include: knowledge; anticipated regret of the negative consequences of sexual risk-taking behaviour and unintended pregnancy; new skills communicating about unintended pregnancy with peers and parents; improved perceptions of self-efficacy in ability to avoid unintended pregnancy; and increased awareness of social influences such as perceptions of: gender norms; peer norms; and parental attitudes, values and beliefs about sexual risk-taking behaviour (Fig. 3).

Following Kirby et al. (2011) the process of developing the theory of change model included the following four steps:

- Identification and selection of the health goal (reduction of unintended teenage pregnancy rates);
- Identification and selection of important related behaviours (abstinence from sexual intercourse and avoidance of unprotected sexual intercourse);
- Identification and selection of important risk and protective factors (targeted psychosocial variables as indicated by theory and research); and
- Identification and selection of intervention components (as described next).

Developing the content and components

This was achieved by defining educational outcomes for each of the user groups (pupils, teachers, teacher trainers and parents) based on the targeted psychosocial variables outlined in the theory of change model and then considering possible activities that might help young people achieve this outcome. For example, one of the targeted psychosocial variables is knowledge about the possible negative consequences of unintended pregnancy on the young person's current life and future goals, which was hypothesised to increase the young person's sense of anticipated regret which might in turn (either independently or interdependently) increase their intention to avoid an unintended pregnancy. The educational outcome associated with this increased knowledge would be that the young person would recognise that unintended teenage pregnancy could have very negative impacts on their life. Potential activities for achieving these outcomes were then developed through some creative thinking or adapted from activities included in other educational programmes. This process was repeated for each of the targeted variables (see Table 2).

Refining the content in consultation

The draft IVD and educational materials were presented at the second steering group meeting and, following minor amendments, we then consulted with teachers, pupils and parents regarding their acceptability. This involved demonstrating drafts of the resources in workshops in Northern Ireland attended by an opportunity sample of RSE teachers ($N = 33$) and parents ($N = 17$), and consulting with teachers (1 male; 1 female) and pupils ($N = 32$; aged 14–16) who took part in a pre-pilot trial run of the intervention in two schools in Ireland (one all boys Catholic; one mixed sex inter-denominational). In this pre-pilot run, teachers were not trained but asked to follow the protocol outlined in the classroom materials as far as pragmatically possible. Although consultants' perceptions of the intervention are unlikely to be representative of the population (and should therefore be viewed with caution), the aim was to gain

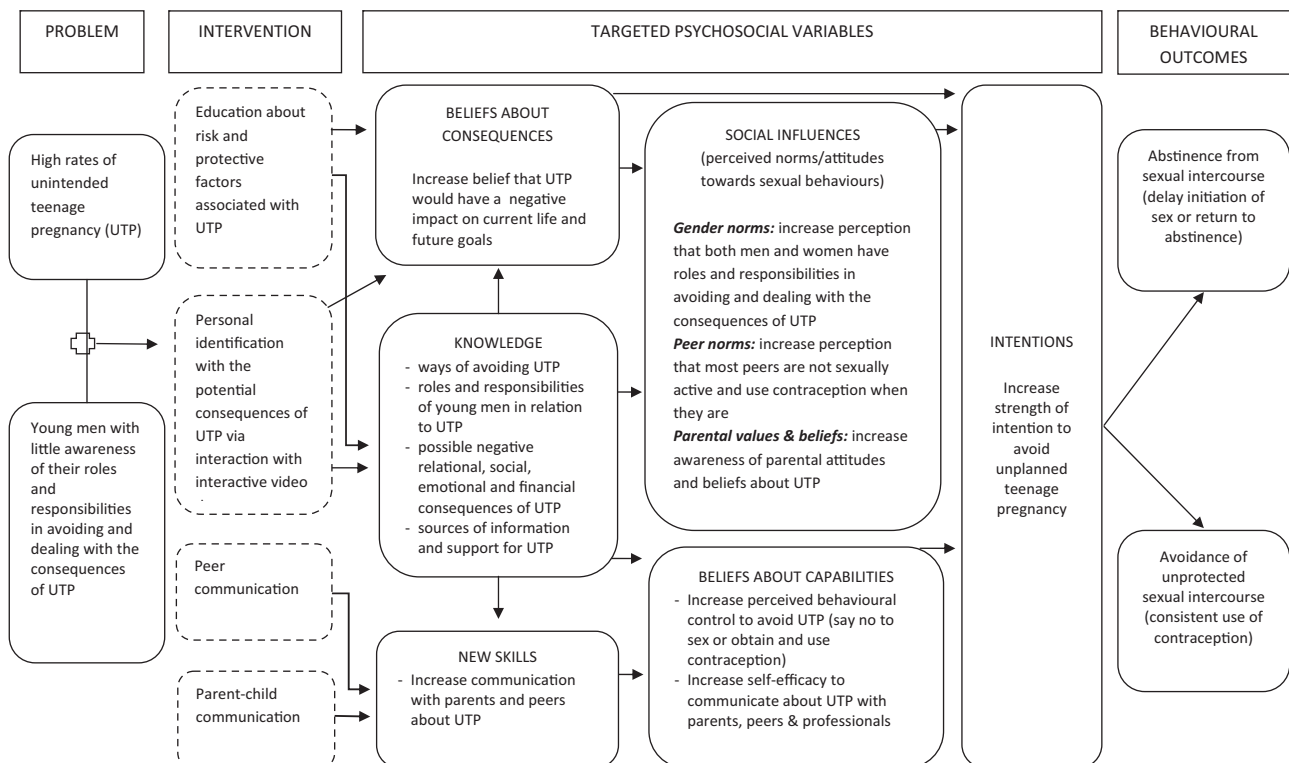


Fig. 3. *If I Were Jack* theory of change model.

preliminary feedback regarding acceptability during the design and optimisation stage of research.

In effect, stakeholders suggested few changes outside of general amendments such as refining and streamlining terminology; adding and removing sources of information for users to the factsheets; providing a letter template for schools to send to parents; and increasing the number of lessons from three to four to adequately space the activities. There were also some suggestions for refinements that were not made. For example, a minority of young people felt that the inclusion of the parent/guardian survey was embarrassing for them and some teachers suggested that they would prefer if they could watch the IVD during all four lessons, stopping it to complete some of the discussion activities and then returning to it during the next lesson. In these cases a decision was made to prioritise empirical evidence over user preference (i.e. research suggests that parent-child communication and connectedness can be important (Wight & Fullerton, 2013) and that the film should be viewed from start to finish in one sitting in order to optimise personal identification with the character and the situation before a process of peer discussion is invoked (Petty & Cacioppo, 1986)). A number of more substantial refinements were also addressed:

Addressing the issue of abortion. Stakeholders were concerned that although the intervention is non-directive in terms of pregnancy outcome options, the fact that it mentions the word 'abortion' might impact negatively on uptake, especially in schools which have an anti-abortion ethos. This issue was addressed by changing the order in which the pregnancy outcome options were displayed in the IVD (i.e. placing abortion second instead of first in the list); including information about the legal status of abortion in Ireland; changing wording that might be interpreted as pro-abortion (e.g. changing 'what are the good things for me about going ahead with abortion' to 'what might be the possible advantages for me of going ahead with abortion'). Additionally, repeated references are made during the teacher training session and in the classroom materials to the fact that teachers have opportunities to state the school ethos and RSE policy and that the intervention allows for this flexibility.

Making it gender sensitive. Although the intervention was developed specifically for teenage men, our preliminary research with educational experts and teachers suggested that it would also be appropriate for use by teenage women. The learning objective was to introduce the topic of unintended pregnancy through the male perspective, arguably a fresh perspective, but to use this as a starting point to discuss both male and female perspectives and to explore similarities as well as differences. Thus, girls are also asked through this intervention to imagine "If I were Jack". In addition, however, and acting on the advice of steering group members and end users, three questions were added to the IVD which referred to how the female character might be feeling. "If I were Jack, how do I think Emma would be feeling now?" Such questions allowed for more inquiry into the female partner's perspective while retaining the focus of the exercise of the imagination as being through the male character (Table 3).

Increasing credibility. We sought to increase the credibility of the intervention to gatekeepers (schools, teachers and parents). This was achieved by developing a dedicated website for the intervention. Among the many features of the website are expert stakeholders' and teachers' audio/video recorded testimonies.

Increasing accessibility. We also developed the IVD for the internet, adapting the previous version, which was delivered to the end user on DVD, and transforming it into the online environment. In summary (see Fig. 4), the intervention features resulted from

consideration of theory and empirical evidence which included primary research, reviews of previous studies and consultation with key stakeholders.

Discussion

Effective RSE interventions require rigorous development processes and transparent reporting to ensure both substantive and process related knowledge transfer. There is currently a dearth of literature addressing developmental processes beyond brief summaries in evaluation studies. The current study benefitted from the guidance provided by the MRC framework for the development and evaluation of complex interventions (Medical Research Council, 2008) and followed the recommended process of identifying the evidence base; identifying theory relating to the phenomenon of young men and teenage pregnancy; and modelling the processes and outcomes of implementing the intervention through preliminary research and consultation with key stakeholders. In applying the framework in the real world we learned lessons, which both complement and extend beyond the guidance which accompanies it, and gained practical insight into a development process which might be useful for others. Three key lessons are summarised in Table 4 and described below.

Know and engage your target population and engage their gatekeepers in addressing contextual complexities

While the MRC guidelines recommend preliminary research in context during the development phase, they do not emphasise the importance of building relationships with the target population and their gatekeepers from the outset.

As recommended by the guidelines, this study began with an in-depth examination of the target population (boys aged 14–17 attending post-primary schools in Ireland) via a systematic review of the literature on their attitudes towards unintended pregnancy followed by primary research which filled a gap in knowledge relating to the psychosocial determinants of their attitudes and decision-making in relation to this phenomenon. This information provided a solid empirically-based foundation on which to build the intervention and pointed to the distinct needs of this group in relation to pregnancy RSE as well as the potential mechanisms which might impact on their intentions to avoid unintended pregnancy. Additionally, by involving teenagers as participants in the production of the IVD and consulting with them at an early stage regarding its appropriateness as a health promotion tool we were able to gauge the acceptability of the IVD and its potential for engaging them from the outset.

Equally important in the process was an element that, although mentioned, is not emphasised in the MRC guidelines. This was our approach to involving gatekeepers and key stakeholders including statutory partner representatives from departments of health and education, RSE specialists, schools, teachers and parents, to help us tackle the contextual complexities which can determine if an intervention actually reaches the target population. The key lesson here was the importance of involving gatekeepers from the outset, thereby enabling planning for potential contextual challenges early in the process as well as, importantly, giving stakeholders and end users some ownership of the intervention.

In developing this intervention, we faced very considerable contextual complexities (e.g. different cultures, educational systems, curricula, mixed/single sex schools). In partnership with stakeholders, we developed a number of strategies to ensure these contextual complexities were addressed. Some of the practicalities of engaging with stakeholders for us included the necessity of face-to-face meetings and bringing together statutory stakeholders from both Ireland and Northern Ireland, a process aspired to under

Table 3

Components of the *If I Were Jack* intervention and targeted psychosocial variables.

Targeted psychosocial variables		Related components of the intervention
Knowledge	Knowledge of ways of avoiding unintended pregnancy	<ul style="list-style-type: none"> • <i>If I Were Jack</i> factsheet • Pause: fast-forward: rewind activity • Modelling of counselling services in IVD
	Knowledge about sources of support for unintended pregnancy	<ul style="list-style-type: none"> • <i>If I Were Jack</i> factsheet • Online scavenger hunt • Parent/guardian survey
	Knowledge about the possible negative relational, social, emotional and financial consequences of unintended pregnancy	<ul style="list-style-type: none"> • Modelling of consequences in the IVD • <i>If I Were Jack</i> factsheet • Making a difficult decision activity • Pause: fast-forward: rewind activity • If I had a baby activity • Parent/guardian survey
	Knowledge about the roles and responsibilities of teenage men in relation to unintended pregnancy	<ul style="list-style-type: none"> • Modelling of male role in the IVD • <i>If I Were Jack</i> factsheet • All discussion activities
Skills	Communication skills to discuss unintended pregnancy with peers and parents	<ul style="list-style-type: none"> • Modelling of verbal scripts in the IVD • Role-play activity • Dilemmas activity • Controversial statements Activity • Parent/guardian survey
Socio-cultural influences	New awareness of peer norms regarding sexual behaviour and unintended pregnancy	<ul style="list-style-type: none"> • <i>If I Were Jack</i> factsheet • All discussion activities
	New awareness of the impact of gender norms and stereotypical beliefs that avoiding and dealing with the consequences of an unintended pregnancy is a woman's responsibility	<ul style="list-style-type: none"> • Modelling of gender norm activity in the IVD • Controversial statements discussion activity • Dilemmas activity
	New awareness of parental attitudes, values and beliefs in relation to unintended pregnancy and unintended pregnancy outcomes	<ul style="list-style-type: none"> • Consideration of personal attitudes, values and beliefs while engaging with the IVD • Making a difficult decision activity • Dilemmas activity • Controversial statements activity • My plan activity
Beliefs about behavioural control	Improved self-efficacy in ability to communicate about unintended pregnancy with parents, peers and professionals	<ul style="list-style-type: none"> • Modelling of communication strategies and verbal scripts in the IVD • All discussion activities • Role-play activity • Parent/guardian survey
	Improved perceived behavioural control in avoiding unintended pregnancy	<ul style="list-style-type: none"> • <i>If I Were Jack</i> Factsheet • Pause: Fast-forward: Rewind activity
Beliefs about consequence	11. Anticipated regret about the negative impact of unintended pregnancy on current life and future goals	<ul style="list-style-type: none"> • Personal reflection while using the IVD and engaging in other activities • Modelling of consequences in the IVD • <i>If I Were Jack</i> Factsheet • Making a difficult decision activity • Pause: fast-forward: rewind activity • If I had a baby activity • Parent/guardian survey • Personal reflection while using the IVD and engaging in other activities • Personal reflection while using the IVD and engaging in other activities • My Plan activity
Intention	Increased intention to avoid unintended pregnancy	

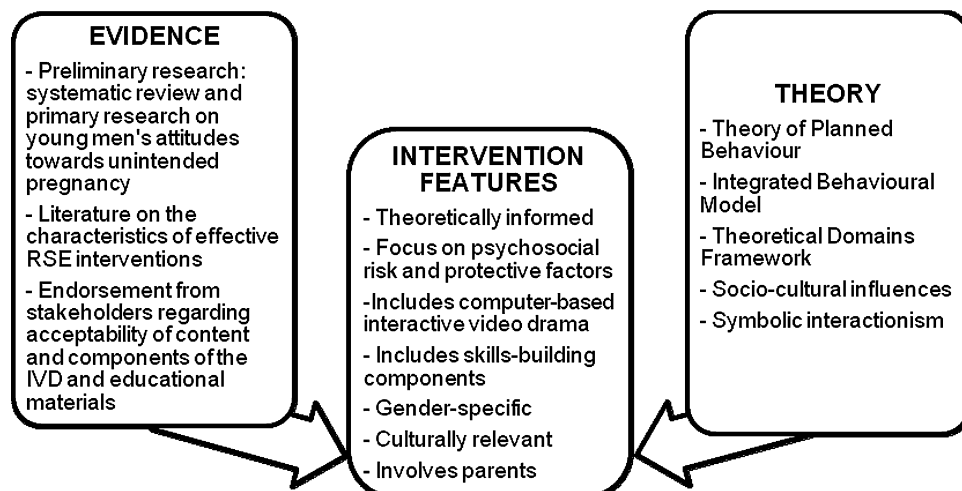

Fig. 4. Evidence and theory-informed framework for intervention development.

Table 4

Design and Development of a film-based RSE Intervention: 3 Lessons learned.

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|--|--|
| (1) Know and involve your target population and engage their gatekeepers in addressing contextual complexities | Systematic reviews
Primary research
Development/adaptation of film script, storyboard and interactive questions
Consultation
Participation |
| (2) Know the behaviours you wish to target and model the process of change | Psychosocial theory
Characteristics of effective interventions
Logic modelling |
| (3) Look beyond development | Consider evaluation, implementation and knowledge transfer from the start |
-

the Belfast Agreement (Northern Ireland peace process) but, as yet, rarely implemented, and certainly pioneering in the field of RSE. It also included ongoing consultation, facing issues head-on to build trust (rather than sweeping them under the carpet), properly facilitated consultation meetings and follow-up with detailed responses to questions. The investment of researcher time in this process alone over one year was considerable. In addition, we shared our draft curriculum materials with the original Australian researchers who in turn engaged in consultation with the primary providers of RSE in South Australia. We also met with teachers, pupils and parent representative organisations to engage them in the development process and asked, at a later date, the same RSE experts and teachers to provide video and audio testimonies for the project website regarding the credibility and value of the intervention. The result of this and other engagement and knowledge transfer strategies (such as workshops at RSE-focused conferences attended by teachers and publications in practitioner-focused journals e.g. (Aventin and Lohan, 2013a,b) has been frequent enquires from teachers and other professionals working with teenagers all over the world regarding their desire to access a copy of the intervention for use with their pupils. Thanks to these efforts and the fact that the intervention so clearly fills a gap in resources for teenage men, we approach evaluation with the expectation that there will be ongoing demand for the intervention. In countries such as Ireland and Northern Ireland, where RSE remains a controversial issue, this is a significant achievement.

Know the behaviours you wish to target and model the process of change

Although the MRC framework highlights the value of identifying and/or developing theory, little guidance is provided regarding how this process should proceed. This study provides a model of how this process might unfold in practice. As outlined in Fig. 1, for us this meant repeating the three steps outlined in the MRC framework twice—first in Stage 1 of our process in relation to understanding the phenomenon within the target group (unintended pregnancy and adolescent men) and then again in Stage 2 in relation to understanding how to change the phenomenon (by increasing intentions to avoid an unintended pregnancy).

Specifically, the iterative process of examining the literature on effective RSE interventions and exploring the relevance and fit of different psychosocial theories and models of behaviour change was both challenging and time consuming. In considering all options in terms of (a) sexual health outcomes; (b) behaviours affecting those outcomes; (c) psychosocial factors affecting each behaviour; and (d) all the activities that might affect each of these factors, there is a compelling impulse (and arguably, a need) to

include every conceivable possibility. This then requires a systematic process of focussing the function of the intervention so that there is a balance between potential efficacy (important mechanisms of change are targeted) and potential acceptability (the intervention can be feasibly delivered within the context for which it is intended). Creation of the logic model and the resulting diagram were immensely useful for focusing this process but researchers working on similar projects are advised to factor in adequate time for this.

Look beyond development

Even the most acceptable and engaging intervention does not deserve a place in the already over-crowded curriculum if its value in improving the sexual health of young people cannot be determined. Conversely, even the most effective intervention will be useless if it cannot be feasibly implemented. An essential part of the development process, therefore, involves thinking about and planning for all aspects of the research process that will follow—feasibility testing; evaluation; implementation, follow-up and monitoring. The guidelines do not, however, indicate the importance of considering *implementation* during *Phase I*, despite the fact that this might alert the researcher to factors which may impact on successful implementation. In discussing *Phase IV* the guidelines indicate that “successful implementation depends on changing behaviour—often of a wide range of people. This requires a scientific understanding of the behaviours that need to change, the factors maintaining current behaviour and barriers and facilitators to change, and the expertise to develop strategies to achieve change based on this understanding.” (Medical Research Council, 2008). It seems likely many of these factors should be considered during the development phase, rather than post-evaluation and this is the approach that we took during the study.

By involving stakeholders in every aspect of the research from the outset, examining the acceptability and feasibility of implementation during preliminary research and consultation, and promoting the credibility of the intervention, we enter the feasibility stage in an advantageous position. During the current study a protocol was developed for a pilot cluster randomised controlled trial and feasibility study in schools in Northern Ireland (Lohan et al., 2014). The study, funded by the UK National Institute for Health Research began in May 2014. As well as determining the feasibility of conducting a large scale effectiveness trial and economic evaluation, the study involves the development of a measure of intention to avoid teenage pregnancy (based on the mechanisms included in the theory of change model), a cost-effectiveness analysis, and a process evaluation which will further examine the acceptability of the intervention to schools, pupils and parents and the feasibility of implementing it in various types of post-primary school in Northern Ireland.

Limitations

The decision to develop and test an existing IVD excluded the possibility of incorporating some components which research suggests might be important components of effective RSE interventions. For example, a recent systematic review of effective sexual health interventions (Shepherd et al., 2010) indicates the importance of building connections with community based sexual health services and providing longer-term programmes—neither of which are emphasised in the *If I Were Jack* intervention. Future development work might seek to develop the intervention further to include these and other evidence-based components.

A potential limitation of the intervention lies in its possible negative impact on teenagers who have had, or are about to have, a child. The intervention strongly emphasises the potential negative

consequences that having a child might have on a teenagers' current life or future goals and, as such, has the potential to reinforce or indeed instigate stigmatisation processes. At present, this potential negative impact is off-set with a teacher training process which emphasises the importance of reminding and discussing with pupils that the resource refers to 'unintended' teenage pregnancy (i.e. a pregnancy that is unexpected and unwanted) rather than teenage pregnancy in general, which for some young people can be a planned and positive experience. Pupils are also informed by the researchers and the teacher that they should contact the school counsellor/pastoral care officer should they find any part of the intervention upsetting. Additionally, as part of the feasibility study we are undertaking focus group discussions with pupils regarding how we might further address this issue.

Conclusions

We have developed a unique, evidence-based, theory-informed intervention that is acceptable to statutory stakeholders, teachers, pupils and parents in two countries, Ireland and Northern Ireland, and is being piloted in South Australia using an Australian version of the IVD (Johnson, 2012). It is based on existing evidence-based RSE programmes targeting unintended teenage pregnancy, includes key behaviour change techniques that are influential in changing sexual behaviour and incorporates sociological understandings of gender norms relating to pregnancy. The intervention is the first to be documented in the scientific literature that specifically addresses teenage men and unintended pregnancy.

While the MRC guidelines (Medical Research Council, 2008) suggest a very useful framework for conducting Phase I research, they provide little description of how this should proceed (relative to guidance provided on Phases II–IV). This effectively relegates the importance of this phase to considerations of summative evaluation, despite growing consensus that the development of conceptually-based, acceptable interventions is of vital importance before proceeding to trial. This is compounded by a dearth of published literature reporting the development of complex interventions in practice. The result is increased potential for misallocation of research labour and resources on what is already a costly and time consuming process. More broadly, as the new mantra of knowledge translation spreads across the academic community there is evermore need to report intervention development processes and intervention components in detail for others seeking to bridge the gap between research and interventions. Reporting on these methodological processes has already directly inspired a research team to develop and evaluate a similar IVD based educational resource on young people and marijuana usage for British Columbia, Canada entitled *Cycles* (University of British Columbia). Consequently, the model of intervention development reported in this paper is presented not as an ideal, but as an exemplar which other researchers might utilise, modify and improve.

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